APPENDIX III, EXHIBIT A

Physician Survey on Immunochemical Fecal Occult Blood Testing for Colorectal Cancer Screening

INTRODUCTION

Background

Colorectal cancer (CRC) is the second leading cause of cancer deaths in the U.S. today despite safe and effective methods for the detection of early stage disease . In 2003, an estimated 28,300 men and 28,800 women will die of CRC[1]. Widely available screening modalities include fecal occult blood testing (FOBT), flexible sigmoidoscopy, colonoscopy, and double-contrast barium enema. Clinical guidelines for use of these modalities differ across various professional organizations[2]. The U.S. Multisociety Task Force on Colorectal Cancer recommends annual FOBT or flexible sigmoidoscopy every 5 years (recommendation based on strong evidence); combined annual FOBT and 5-year flexible sigmoidoscopy (based on theoretical evidence); double-contrast barium enema every 5 years or colonoscopy every 10 years (based on strong rationale)[3].

The most frequently used CRC screening test in the US. is the guaiac-based (GB) FOBT. GB-FOBT detects hemoglobin in stool, an indicator of excess bleeding characteristic of neoplasms of the colorectal mucosa. The patient applies stool samples to a guaiac-impregnated test card which turns blue in the presence of pseudoperoxidase enzyme in hemoglobin and hydrogen peroxide developer[4]. The card can be rehydrated with drops of water to increase sensitivity, although rehydration results in decreased specificity, and hence, an increased percentage of false positives. A number of GB-FOBTs are commercially available, including Hemoccult II, the most widely used one in the U.S.[5]. The Hemoccult SENSA is an alternative GB-FOBT that was recently endorsed as the test of choice by the World Health Organization[6]. Hemoccult SENSA has higher sensitivity than Hemoccult II, although specificity is higher only relative to the rehydrated Hemoccult II test.

GB-FOBT is not specific for human blood, and therefore, false positives may occur from detection of exogenous plant and animal substances in the diet. Therefore, dietary exclusion of red meat, certain vegetables, vitamin C, and non-steroidal anti-inflammatory drugs is required before and during the 3 serial stool sample collections. Dietary exclusions may be associated with issues of patient acceptance and compliance, which may ultimately become barriers to effective test utilization. In contrast, immunochemical (IC) FOBTs, which rely on the specific detection of human globin proteins found in the large intestine, are an alternative type of test with no required dietary restrictions[6]. However, IC-FOBT may require a centralized laboratory setting, unlike GB-FOBT which can be developed and interpreted in an office setting, thus costing more and extending the time until results are available.

Currently, little is known about physician use and knowledge of, and attitudes towards IC-FOBT, particularly in comparison to GB-FOBT. The NCI will support a national survey targeting primary care

physicians and a control group of gastroenterologists, designed to obtain national data on these topics, as part of an effort to track the utilization of FOBT screening modalities in the U.S.

The General Scope of Work

The survey will use a questionnaire with elements outlined in preliminary form in Appendix III Exhibit A.1. The objectives of the survey are to determine the relative utilization of these tests by physicians at the national level; to ascertain physician knowledge of available GB- and IC-tests, to examine physicians' general attitudes towards testing, and; to explore possible variation in utilization and knowledge/attitudes by medical specialty, type of practice, year of training completion, board status, urbanicity, and geographical region. For comparison, limited information on use of other cancer screening tests will be ascertained where applicable to the medical specialty.

The primary hypotheses are that:

1) Primary care physicians in the U.S. who are located in urban areas, practice in relatively high SES census tracts, completed their training in recent years, and regularly refer patients for other cancer screening tests have statistically significant:

a) greater levels of self-reported knowledge, current use of, and future intentions to use IC-FOBT; and
b) fewer perceptions of barriers to use of IC-FOBT (e.g., lack of insurance coverage; few available testing laboratories; lack of scientific evidence of test accuracy; patients not willing to accept test, etc.)

2) Relative to gastroenterologists, internal medicine, family, and general practitioners have a statistically significant lower level of self-reported knowledge, current use of, and future intentions to use IC-FOBT for CRC screening, as well as significantly greater perceptions of barriers to testing.

3) Within specialty subgroups, there is variability in the level of self-reported knowledge, current use of, and future intentions to use IC-FOBT for CRC screening, and in perceptions of barriers to testing, by type and location of practice, recency of training completion, and frequency of patient referral for other cancer screening tests.

The Contractor will identify a sampling plan which allows for statistically stable comparisons of questionnaire responses between targeted physician subgroups specified by NCI (see Statement of Work). The Contractor will also specify survey methods which optimize response rates, including but not limited to, how the survey instrument should be administered, whether administration should be mixed-mode or specific single mode, what type of preliminary contact with respondents is necessary, and how many attempts at contact should be made. The Contractor will work with NCI project officers to complete survey instrument development, and will subsequently pilot test and refine the instrument prior to initiating the survey. The Contractor will also prepare the documentation required by the Office

of Management and Budget for clearance. The Contractor will field the study, providing the NCI with scheduled progress reports, and will computerize and clean the data, providing statistical analyses to the NCI as requested.

Preliminary Sample Size Estimates

The basis for sample size estimation is the size of the population of interest, minimization of sampling error, and anticipated response and ineligible rates. It is anticipated that a stratified random sampling design will be used, with physician specialties and, possibly, practice location (Metropolitan Statistic Area (MSA) vs. non-MSA) as stratifying variables. In the U.S. in 1993, there were 193,406 physicians meeting our definition of primary care practitioner, including 52,362 family practitioners, 19,323 general practitioners, 86,102 general internists, and 8,366 gastroenterologists[7]. About two-thirds of these physicians (n = 198,039) were non-trainee practitioners who actively saw patients.

Given this population size, a margin of error not exceeding $\pm$ 3% for point estimates, a minimum 65% survey response rate[8], and a 10% ineligible rate (due to physicians in the sampling frame who are subsequently identified as being retired, deceased, not practicing primary care medicine, or having an unknown or incorrect address), we estimate a sample size of 1,538 primary care physicians will be required to obtain 1,061 completed questionnaires[9]. The estimated sample size is adequate to detect a two-fold higher proportion of urban (MSA) primary care physicians intending to use IC-FOBT, relative to primary care physicians in rural (non-MSA) practice locations, at 90% power, 0.05 level of significance, and in a 2-tailed test. It should also ensure estimates of reasonable precision, and permit the simultaneous analysis of multiple covariates.

The final number of cases to be sampled will be determined by the Project Officer in collaboration with the Contractor. The final sample size could increase if it is decided that it is desirable to over-sample certain strata of physicians because there is particular scientific or policy interest in the characteristics of these health care providers or the population groups they serve.

The Contractor shall conduct their own sample size calculation estimates considering the primary hypotheses (described above) to be tested. In the absence of a priori data on the prevalence of IC-FOBT, intention to use these tests, and barriers to testing in the referent subgroups (e.g., physicians with a practice located in rural (non-MSA) or low SES areas, training completed at least ten years ago, general/family practicioner, etc.), assumptions made for purposes of sample size calculations should be clearly stated by the Contractor. Calculations should assume a 0.90 power to detect a minimum twofold increase in the likelihood of a response ("relative risk"), given a two-sided alpha level of 0.05. The following is an example of the type of sample size estimates that should be presented by the Contractor:

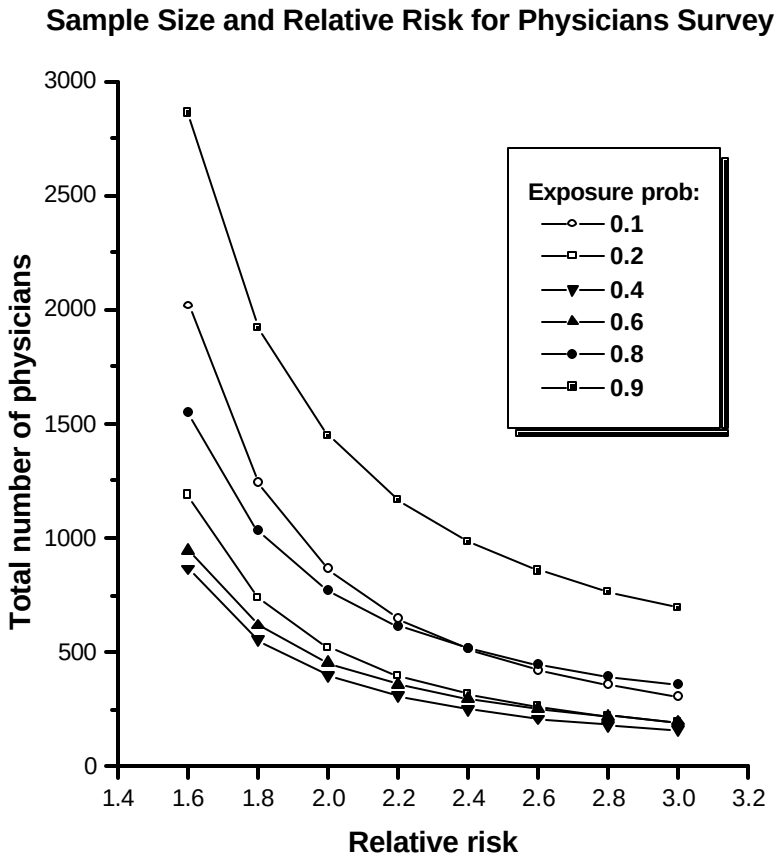
To test the hypothesis of a two-fold greater likelihood of intention to use IC-FOBT among practitioners in high vs. low SES areas, six possible sample size scenarios were estimated (see Figure 1) assuming probabilities of intent to use of 0.1, .2, .4, .6, .8, or .9 among low SES-area physicians (power = 0.90; α = 0.05). Based on hypothetical data that 63.5% of physicians would consider using IC-FOBT in lieu

of GB-FOBT, a nonuser/user ratio (i.e., "control to case" ratio) of approximately 0.5 was assumed. If 10% of low SES-area physicians stated an intent to use this test, 863 respondents (575 users and 288 nonusers) would be required to detect a two-fold greater likelihood of use in high vs. low SES-area physicians.

The information above assumes no confounding or effect modification. However, the Contractor should also consider the need to control for confounders or assess effect modification through multivariate analysis when presenting sample size estimates. Also, the final sample size should account for non-response. Additional examples of sample size estimates should be provided for testing the hypothesis of differences between primary care physicians vs. the comparison specialty groups mentioned in Task 3.

Since it is expected that non-responders to this survey may have different characteristics than responders, the Contractor shall consider the problem of non-response bias in the sample design of the survey and devise methods of data collection that will facilitate correction for non-response bias in the analysis of the data. The AMA Physician Masterfile, which has been used in other national physician surveys (2) could be used to compare the characteristics of responders and non-responders with regard to available characteristics to better describe the nature of the non-response bias. The Contractor should also consider methods of weighting to adjust for non-response for the analysis (weighting done by specialty type, size of practice, solo vs group, etc.).

FIGURE 1


Sample Size and Relative Risk for Physicians Survey
Total number of physicians
Relative risk
Exposure prob:
0.1
0.2
0.4
0.6
0.8
0.9
3000
2500
2000
1500
1000
500
0
1.4
1.6
1.8
2.0
2.2
2.4
2.6
2.8
3.0
3.2

STATEMENT OF WORK

Task 1 - Survey Instrument Design

A draft of the elements to be included in the survey instrument is included in Appendix A. Using these elements, the Contractor shall develop, revise, format, and finalize an instrument for mail and/or telephone interviews which is designed to elicit valid responses, based on discussion with Project Officer(s) and Pilot testing. A brief supplemental questionnaire may be included for selected medical specialties. The contractor should consider an instrument equivalent to 15-20 minutes response time. The instrument design and general survey plan should reflect this consideration. The Contractor shall determine whether the survey should use mailed, telephone, or Web-based surveys, or a mix of the three. Because physicians are a difficult population to survey, the Contractor should consider any and all mechanisms, including monetary reimbursement for time spent, to obtain an acceptable response rate. The proposal should explain the trade-off between optimizing response time vs. maximizing response rate.

In formulating the instrument design and general survey strategy, the Contractor should consider employing, as consultants or subcontractors, researchers who have had experience in conducting surveys of physicians, as well as professional organizations. This may include, but is not limited to, the American Medical Association, American Gastroenterology Association, and American College of Physicians. The Contractor shall submit the draft instrument for review by the Project Officer(s) in accordance with the delivery schedule.

Task 2 - Preparation of OMB Clearance Package

The Contractor, in consultation with the Government Project Officer(s), shall produce all necessary documentation to be submitted to the Office of Management and Budget for OMB clearance.

Task 3 - Obtaining the Universe of Physician Specialists

In order to obtain a list of the addresses of all targeted physician specialties in the U.S., the Contractor should consider consulting published lists of physician specialty colleges or organizations such as the American Medical Association (AMA) or American Osteopathic Association (AOA). For example, the AMA's database contains more than 650,000 physicians (including non-AMA members), with variables on physician practices, including name, address, phone number, and specialty. The primary care specialities to include in the survey are general and family practice, and internal medicine. For comparison purposes, gastroenterology (a subspecialty of internal medicine) should also be included. These specialties traditionally conduct and/or refer for CRC screening.

Task 4 - Survey and Sampling Design

The Contractor shall design a study that comes as close as possible to meeting or exceeding the Government's criteria for precision. If this degree of precision is found, during the course of the study, to be unobtainable within the cost constraints of the study for some or all of the information sought, the Contractor shall present an analysis of the tradeoffs between cost, precision, and elimination of some of the survey items and the survey design will be modified in consultation with the Project Officer.

The Contractor shall provide a mechanism for selecting a nationally-based random sample of physicians out of the universe specified in Task 3. The method used to select the sample must be provided and justified by the Contractor. The sample drawn should include mainly primary care physicians, along with the additional comparison subgroups mentioned in Task 3, representing all regions of the continental US, and should also reflect a mix of urban, suburban, and rural practice settings that are in proportion to national practice settings. The Contractor will consider the possibility of linking physician information (via the address) with Census data on socioeconomic characteristics of the served populations at the census tract level. This would permit stratification of the sample of physicians according to high versus low socioeconomic status populations, and thus enable comparisons of physician knowledge and practices across diverse practice settings. The users of the survey will also be interested in analyzing differential responses by physician specialities. The Contractor shall submit a sampling strategy which is consistent with the above considerations and may incorporate stratification by region and urban/rural location, if such stratification is feasible within the overall cost and precision criteria of the study.

The survey will involve diverse categories of physicians including: 1) physicians engaged in clinical practice, in solo or group practice settings, and 2) physicians engaged in both clinical practice and research within research institutions (e.g. academic medical centers, research oriented managed care, research facilities, university hospitals).These samples should include a range of practice styles (solo vs. group) and health systems (Networks, PPO, IPA, salaried HMOs). Ineligible physicians include retirees, physicians involved in teaching, research or administration who are not engaged in any clinical activities, and physicians in training who are not yet board eligible for their speciality.

The Contractor shall consider the key hypotheses to be tested (see Introduction) when estimating a proposed survey sample size. In the absence of a priori data on the prevalence of IC-FOBT tesing, intention to test, and barriers to testing in the referent subgroups (e.g., physicians with a practice located in rural or low SES areas, training completed at least ten years ago, general/family practitioner, etc.), assumptions made for purposes of sample size calculations should be clearly stated by the Contractor. Calculations should assume a 0.90 power to detect a minimum twofold increase in the likelihood of a response (“relative risk”), given a two-sided alpha level of 0.05.

For example, to test the hypothesis of a two-fold greater likelihood of intention to use IC-FOBT in lieu of GB-FOBT among practicioners in high vs. low SES areas, six possible sample size scenarios were estimated (see Figure 1 in Introduction) assuming probabilities of intent to use of 0.1, .2, .4, .6, .8, or .9 among low SES-area physicians (power = 0.90; " = 0.05). Based on hypothetical data where 63.5% of physicians would consider using IC-FOBT, a nonuser/user ratio (i.e., "control to case" ratio) of approximately 0.5 was assumed. If 10% of low SES-area physicians stated an intent to use this test, 863 respondents (575 users and 288 nonusers) would be required to detect a two-fold greater likelihood of use in high vs. low SES-area physicians.

The above curves assume no confounding or effect modification. However, the Contractor should also consider the need to control for confounders or assess effect modification through multivariate analysis when presenting sample size estimates. Also, the final sample size should account for non-response of 20%. Additional examples of sample size estimates should be provided for testing the hypothesis of differences between primary care physicians vs. the comparison specialty groups mentioned in Task 3.

Since it is expected that non-responders to this survey may have different characteristics than responders, the Contractor shall consider the problem of non-response bias in the sample design of the survey and devise methods of data collection which will facilitate correction for non-response bias in the analysis of the data. The AMA Physician Masterfile, which has been used in other physician surveys[10] could be used to compare the characteristics of responders and non-responders with regard to available characteristics to better describe the nature of the non-response bias. The Contractor should also consider methods of weighting to adjust for non-response for the analysis (weighting done by specialty type, size of practice, solo vs group, etc.).

Task 5 - Pretest of Survey Instrument

The survey instrument shall be pre-tested on a limited sample of physicians to demonstrate that the instrument and general survey approach are designed to obtain adequate response rates (i.e., adequate number of physicians willing to participate in the survey and adequate responses to each item of the survey) and that the questions can be answered in the time budgeted for the survey. It is especially important that the performance of the survey instrument/general survey strategy be demonstrated in regard to obtaining the data. Recognizing the traditional difficulties of obtaining adequate reponse rates in physician surveys[11], the Contractor should consider previously proposed methods to increase physician response rates[12,13]. If the survey fails to meet these criteria in the pre-test phase, the survey must be modified by the Contractor in consultation with the Project Officer(s). The Contractor should obtain a response rate that will conform with OMB standards.

Task 6 - Data Collection Methods

The Contractor shall prepare and deliver specifications and documentation for a rapid and accurate system to collect and track mail and/or telephone interview data. Interviews will be conducted on a sample of physicians as described above.

The Contractor and the Government will assure that the questionnaire will have proper skip patterns, potential response categories, and interviewer prompt cues. The Contractor will be responsible for all steps necessary to provide advance notice to the potential respondents. Final production and copies of the questionnaire will be the responsibility of the Contractor.

Task 7: Interviewer Hiring, Training and Monitoring

Sub-task 7a: Interviewer Hiring

The Contractor will provide the services of a sufficient number of trained interviewers and other necessary personnel to complete the required number of interviews, and other data collection efforts, in the specified time frame.

Sub-task 7b: Interviewer/Record Reviewer Training

The Contractor shall develop and conduct a standardized and documented training program for all interviewers and supervisors which applies standard interviewing and administrative procedures to the administration of the questionnaire. The program shall be documented in an Interview Instruction Manual. Training materials and a formal plan for training and evaluation shall include the following:
1) An explanation of the survey emphasizing its purpose and importance, and the need to maintain a positive image with the interviewees (in order to maximize response rates to critical questionnaire items);
2) The administrative specifications of the study, including dates of the scheduled interviews, time of day, number of call backs and call back rules, refusal conversion strategies, reporting procedures, quality control procedures, and instructions for selection of eligible respondents; and,
3) Detailed review of all questions including definitions of terms, response categories, question by question instructions, methods of probing and recording, and any other points which need clarification. The interviewer training program will be conducted by the Contractor and will include non sample practice interviews. Training, including listening to actual interviewing, will be monitored by the Project Officer.

Sub-task 7c: Quality Control of Data Collection

The Contractor shall develop a systematic process to monitor the performance of the interviewers during the field period, including performance criteria and methods to identify substandard interviewers, with provisions to either improve their performance or replace them. A sufficient sample of actual interviews are to be monitored to assure quality control.
Provisions to allow the Project Officer to monitor actual interviews shall be described.

The Contractor will work with the Project Officer(s) to provide a review of the background and goals of the study which will serve as the basis for an interviewer training manual and a question by question explanation of all questionnaire items, including interviewer probes. The Contractor is expected to incorporate these study-specific tools into an appropriate training program which will include standard interviewer training techniques. The Project Officer(s) will review all manuals, instructions, etc. and these materials will be modified in response to reviewer comments before they are put into use.

Task 8: Obtaining Completed Questionnaires

The Contractor shall obtain the required number of questionnaires by using the systematic procedures developed and pretested for data collection. A completed questionnaire shall include all critical questions answered completely. Critical questions will be identified by the Project Officer(s). The Contractor should track the data collection and produce periodic reports regarding response rates (see subtask 9b). The Contractor will consult with the Project Officer(s) to discuss these response rates, in order to modify data collection or other methods if response rates are less than expected.

Task 9: Data Handling

Subtask 9a: Data Storage

The Contractor shall develop and implement a system to be used by itself and any subcontractor(s) to code, edit, verify and store the data as it is collected. The Contractor shall provide to NCI a clean raw data file for the survey containing the data from the completed questionnaires (by ID number), plus all disposition reports obtained by the Contractor and any subcontractor(s). The machine readable format of the file to be used will be specified by the Projects Officer(s). The Contractor is responsible for insuring that any subcontractor(s) collects and transmits data to the Contractor in a manner that will enable him to merge multiple data files into the master format specified by the government in a rapid, cost efficient and

practical manner. Procedures to track and log the disposition of all questionnaires at the various stages of the process should be described. The procedures shall be documented in a data collection management manual. A formatted analytic file for statistical analyses will be developed from the raw data file. Complete documentation shall be supplied for each of the data files generated which includes: a list of variables, codes, coding rules, edit specifications, edit flags, and a data dictionary.

Subtask 9b: Interim Tabulations and Progress Reports

Monthly progress reports shall include updates and evaluations of the survey operation as well as complete tabular summaries of the interview data. Both cumulative and month-specific data should be presented. During the field period, a weekly status report will also be required. The interim data should also be presented in graphical chart format to permit visual interpretation.

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Information in these reports, at a minimum, shall include:

1) Number and percent of physicians for whom contact was attempted, indicating whether they were new or repeat contacts. Also show number and date of contact attempts per physician and result of contact efforts for each date of attempt.
2) Number and percent of physicians who completed the questionnaire.
3) Number and percent of physicians who Contractor attempted to contact but who did not complete the questionnaire, in total and by category of non-response (i.e., correct address and/or phone number could be not ascertained; refused; not located; re-scheduled, etc.).
4) Number of respondents and non-respondents by physician demographic group (i.e., age, sex, region, urban/rural, speciality, type of practice).
5) Number of refusals, point where the refusal occurred if during direct interview, reason for refusal and number of refusal conversions.
6) Response frequencies for individual questions (for monthly reports only).

Subtask 9c: Data Analysis

In the proposal, the Contractor should describe the analytical plan which would include the following analyses described below. The offeror shall also include a description if any, of other relevant analyses not detailed here, a rationale for additional suggestions, and budget implications.

After completion of the data collection, the Contractor shall: 1) construct an appropriate analytical file using statistical software approved by the Project Officer(s); 2) perform statistical analysis of the data

collected and produce a hard copy of such analyses; 3) present and summarize selected results in tables. The Project Officer(s) shall direct all analyses and receive a hard copy of the above analytical runs from the Contractor.

The following analyses shall be performed;

1) Distributions of all questionnaire response variables .
2) Distributions of all physician demographics (age, sex, region, speciality, urban/rural, type of practice, board status, year of completion of specialty training).
3) Cross-tabulations of physician demographics and questionnaire response variables.
4) Multivariate analyses to determine predictors of response, as directed by the Project Officer(s)..

Task 10: Final Report

A final report describing the survey protocol, including sampling and survey methods for the pilot and main survey, final response rates and distribution of non-respondents by reason for non-response, data editing and storage details, problems encountered (with documentation of process), and modifications made during the survey shall be provided to the Project Officer(s). This report should be delivered no later than eighteen months after the award of the contract.

PROTECTION OF HUMAN SUBJECTS/PRIVACY ACT NOTIFICATION

This procurement action requires the Contractor to do one or more of the following: design, develop, or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 95-579, December 31, 1974 (U.S.C. 552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties.

PUBLICATION AND PUBLICITY

The Contractor agrees that he shall not publish, have published, or otherwise disseminate any information of whatever nature resulting from the work being performed under this contract without prior approval in writing from the designated Project Officer, to whom he shall submit a copy of any manuscript proposed for publication; and that published material will bear an acknowledgment of Government support in the manner and form prescribed by the Project Officers. Release of data files and tapes containing files is not permitted unless approved in writing by the Project Officer.

Data (source documents, data files) and computer software shall be collected, maintained and/or developed under this contract. The Contractor is obligated to function under the rules and regulations which apply to the collection of data on human subjects. As a contractor for DCCPS, the System of Records of subjects in cancer studies established and approved for DCCPS, NCI, NIH, and DHHS must apply. Data are the property of the NCI and are not to be made available to any individual, group, or institution without the approval of the Project Officer. Data which are a part of a study in progress are not in the public domain until the study is terminated, the data files have been edited, documentation for creation of the data base has been completed, descriptions of the file structure and contents have been approved for release, and data are available as public use files. Data are to be used, maintained, disclosed and disposed of by the Contractor only as approved by the Project Officer. Data forms will be stored at the Contractor's place of business. No data will be released without the written consent of the Project Officer. Upon completion of the contract, all data forms shall be returned to the Project Officers and computerized files will remain in the possession of the NCI.

All computer software developed under this contract is the property of the Government and cannot be sold or disseminated without Government approval.

PERIOD OF PERFORMANCE

The performance period of this contract will be for 21 months. This will be funded on an incremental basis. It is anticipated that the contract will begin approximately October 1, 2004. The initiation date may be earlier or later, depending on the progress of the competitive procedure.

REFERENCES

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APPENDIX III Exhibit A

12. Asch DA, Christakis NA, Ubel PA. Conducting physician mail surveys on a limited budget. Medical Care 1998;36:95-99.

13. Urban N., Anderson GL, Tseng A. Effects of response rates and costs of stamps vs business reply in a mail survey of physicians. J Clin Epidemiol 1993;46:455-459.

APPENDIX III Exhibit A

DELIVERABLES

The Contractor shall prepare and submit the following reports and other deliverables in the manner stated below:

1) WEEKLY STATUS REPORTS/ MONTHLY PROGRESS AND BUDGET REPORTS

As described in the Statement of Work (Subtask 9b), weekly status reports will be provided to the Project Officer(s), due by Friday of the following week (or the next Monday if Friday is a holiday). By the tenth of each month, the Contractor shall submit a written Monthly Progress and Budget Report to both the Project and Contract Officers that documents and summarizes work performed during the previous month, as described in Subtask 9b. Any difficulties experienced during the conduct of the study shall also be highlighted and suggested resolutions shall be made. The level of specificity required is person hours by personnel category. Cumulative dollar figures shall also be provided and compared to planned costs of the tasks. The report shall cover the first calendar month following the effective date of the contract, in addition to any fractional part of the initial month. The Contractor will be required to meet with the Project officer(s) and other NCI staff on a regular basis.

2) TASK ORDER FINAL REPORT

The Contractor shall submit a written Task Order Final Report by the expiration date of the contract. The report shall include a summation of the work performed and salient results obtained for the entire contract period of performance, as described in Task 10 of the Statement of Work. The Contractor shall submit with the Task Order Final Report, a Summary (not to exceed 200 words) of salient results achieved during the performance of the contract. The Task Order Final Report shall be in sufficient detail to describe comprehensively the results achieved. The Task Order final report shall include: 1) an inventory of all documentation maintained (and modified) by the Contractor during the period of the contract (including users manuals, coding manuals, test instruments, etc.), a copy of all tapes, diskettes, and data sets with automated documentation which is in accordance with the standards specified by NCI staff; 2) a list of any CIT accounts, initials, keywords, and RACF passwords used by the Contractor if applicable, plus an inventory of all tapes, diskettes, and data sets assigned to accounts, and a brief description of each.

The Contractor shall provide the Contracting Officer and the Project Officer(s) with a copy of the Task Order Final Report in draft form 60 calendar days prior to its scheduled delivery date. The Project Officer(sd) shall review the draft report and provide the Contractor with comments within 14 calendar

days after receipt. The Final Report shall be revised if necessary and the final version delivered within 14 calendar days after receipt of comments from the Project Officer(s).

3) COMPUTER FILES

Computer files of collected and edited data, including raw IBM-compatible files and files formatted for statistical analyses using software approved by the Project Officer(s), shall be provided as requested by the Project Officer(s). Data will be requested periodically throughout the contract period. At the end of the contract, data files of all collected information and appropriate documentation shall be provided to the Project Officer(s).

APPENDIX III Exhibit A

TECHNICAL PROPOSAL INSTRUCTIONS SPECIFIC TO THIS PROCUREMENT

1) PERSONNEL

The Offeror shall provide the necessary support staff to carry out all aspects of the workscope. This should include a project director, survey operations manager, statistician(s), programmer/analysts, technical support personnel, and administrative/clerical support. The Offeror shall fully describe the responsibilities of each member of the team proposed and how this team can meet project needs. The proposal should document the relevant experience of any persons proposed by enclosing their CVs and shall justify the need for persons with various capabilities. The proposal should demonstrate that the appropriate personnel have received required education in the protection of human subjects, in accordance with NIH policy found in the NIH Guide for Grants and Contracts. Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial entitled "Protection of Human Research Subjects: Computer-Based Training for Researchers", available at http://www.nihtraining.com/ohsrsite/.

A. Project Director (Masters level or above)

The Project Director should have at least 5 years of experience designing and directing health services research projects, including provider surveys. Experience should include:

1. Substantial scientific understanding of health services research.
2. Demonstrated ability to contribute to the design of health care provider surveys.
3. Conduct of surveys that achieve maximum response rates and optimal data quality.
4. Collaborative work with scientific investigators in the design and conduct of provider surveys, and publication of results.
5. Overall management of survey operations and support staff.

B. Survey Operations Manager (Masters level)

The Project Manager should have at least 5 years of experience managing personnel and directing studies that involved:

6. conducting large population surveys such as surveys of national samples.
7. developing and administering questionnaires, including those directed to physicians.
8. maintaining participation rates conforming to government standards, converting potential

dropouts.
9. assessing reliability and validity of collected data.
10. editing and analyzing questionnaire data.
11. preparing a package for Office of Management and Budget review.

C. Programmer/Analyst

The Programmer/Analyst should be experienced in supervising personnel, writing and implementing data management systems, and manipulating and analyzing large data sets.

D. Statistician (Ph.D.)
The statistician should have at least 5 years of experience in:

12. the design and choice of sampling frame for nationally-based studies,
13. sampling of selected occupational subgroups, preferably physicians.

The proposal may include technical support personnel such as telephone supervisor, telephone interviewers, data entry person and data supervisor. The Government's Requirement for the work set forth in the Statement of Work of this solicitation is estimated to be 3655 direct labor hours. These hours are not restrictive for the proposal purposes and are provided as a guide. It is estimated that the labor hours are constituted as specified below and will be expended approximately as follows:

Labor Category	**Year 1 Labor Hours**	**Year 2 Labor Hours**	**Total**
Project Director	325	325	650
Survey Operations Manager	400	400	800
Statistician	75	75	150
Telephone Center Supervisor	50	150	200
Telephone Interviewers	75	200	275
Data Manager	30	200	230
Data Coders	50	400	450

APPENDIX III Exhibit A

Programmer Analyst	250	250	500
Secretary	200	200	400
Total Direct Labor	1455	2200	3655

2) METHODS/APPROACH

The proposal should state the overall objectives, the specific accomplishments to achieve, and the relevance of comparable work in progress elsewhere. A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished and how the project is to be organized, staffed, and managed. The technical approach should be in as much detail as necessary to reflect a clear understanding of the nature of the work being undertaken. Information should be provided which will demonstrate an understanding of management of important events and tasks. The technical approach should also include a discussion of any potential problems and quality control concerns and how these issues will be handled and solved.

A. The technical proposal should describe in detail, justify, and document:

14. Procedures for preparing a package for approval by the Office of Management and Budget.
15. The design of a sampling frame for a nationally-based study of physicians.
16. Procedures for collecting and analyzing data.
17. Procedures for surveying physicians in as cost-efficient manner as possible.
18. Procedures for creating, editing, and processing the questionnaire.
19. Procedures for maintaining participation in the study including acceptable response rates which conform to OMB standards.
20. Procedures for maintaining quality control, including those verifying that collected and coded information and keypunching of data are as complete and accurate as possible.
21. Procedures for editing all data collected.

3) CORPORATE EXPERIENCE AND RESOURCES

Offerors should document their corporation experience and resources relevant to work identified in the Statement of Work of the RFP. This should include:

A. Corporate experience in the area of survey, epidemiologic and health services research, specifically

with studies that involved:

22. developing questionnaires, especially those targeting physicians.
23. selecting nationally-based population samples and sub-samples for studies.
24. administering telephone interviews, mail, and Web-based surveys.
25. effective scheduling and managing multiple contacts with participants.
26. sustaining and tracking response rates throughout a study with multiple contacts.
27. quality control
28. editing and analyzing questionnaire data.

Offerors should describe available resources and facilities necessary to complete the project. This should include a centralized office in which documents and files associated with this study can be stored and secured to ensure privacy. The office should be located so that stored materials can be reviewed and reports and materials received and delivered as specified in the Statement of Work.

4) SCHEDULE

The proposal should include a schedule for completion of work and delivery of items specified in the Statement of Work.

5) OTHER CONSIDERATIONS

Describe any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship. Describe unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

BUSINESS PROPOSAL INSTRUCTIONS SPECIFIC TO THIS PROCUREMENT

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit. Include a cover sheet with name and address of Offeror, and proposed cost and/or price, profit or fee, and total.

APPENDIX III Exhibit A

Provide a time-phased (yearly) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimation in each case. Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Show fringe benefits as a separate line item and include the rate. Show indirect costs, including cost breakdowns, and show general and administrative costs with and without the fee. Travel costs should be estimated where appropriate.

The following direct costs items other than labor are assumed for purposes of estimation and are not restrictive for the proposal purposes:

Other Direct Cost Items

Materials and Supplies
Postage
Copying
Printing
Participant remuneration
Telephones

APPENDIX III Exhibit A

APPENDIX III EXHIBIT A.1

Questionnaire Elements

List of variables to be obtained from sampling frame data base, or if not available, through inclusion in the questionnaire:
medical specialty, type of practice, year of medical school graduation, year of specialty training completion, board status, year of (sub)speciality board exams, urbanicity, and geographical region.

List of Elements to be developed as Questions for Physician Survey on IC-FOBT for CRC Screening

Have you ever directly ordered an IC-FOBT?

Have you ever directly referred patients elsewhere for an IC-FOBT?

In what year did you start referring patients for these tests?

How frequently do you refer patients for the following CRC screening tests on patients age 50 and over: GB-FOBT, IC-FOBT, flexible sigmoidoscopy, colonoscopy, double-contrast barium enema?

Where do you refer patients for testing?

Do you intend to use IC-FOBT in asymptomatic patients in the future?

In your opinion, how do IC-FOBT compare with GB-FOBT in terms of sensitivity, specificity, acceptability to patients, cost, and insurance coverage?

Compared to GB-FOBT, do you think IC-FOBT will become more frequently used in your daily practice in the future?

Do you feel you have the knowledge to recommend these tests?

Would you like continuing education in this area?

Do you feel there is a current need to develop professional guidelines for IC-FOBT use?

APPENDIX III Exhibit A

If yes, what organizations do you consider credible sources for guidelines?

In your opinion, do dietary restrictions influence patient acceptance of GB-FOBT?

How frequently do patients that you recommend for GB-FOBT express concerns about adherence to dietary exclusions?

How frequently do you routinely refer patients for the following screening tests: pap smears, mammograms?

Have you been approached, in person or by telephone or mail, by any companies marketing IC-FOBT?

Are you aware of specific brands of IC-FOBT tests?

Approximately what percent of your patients are covered by managed care?

Including yourself, how many physicians work in your practice?

Do you as an individual have an affiliation, such as an adjunct or clinical appointment, with a medical school?

In a typical day, how many patients do you see?